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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,293	05/07/2001	Robert Falotico	CRD-0931	2210

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AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/850,293	Applicant(s) FALOTICO, ROBERT	
	Examiner Kathryn Ferko	Art Unit 3743	3

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 19, 2002. It appears that claims 1-15 are pending. The REMARKS section of the amendment on page 4, states claims 1-16 are pending. However, it does not appear that a claim 16 has been presented for consideration.

Response to Arguments

1. Applicant's arguments filed December 19, 2002 have been fully considered but they are not persuasive.

According to the specification on page 10, remodeling is defined as "...a process whose mechanism is not clearly understood but which results in shrinkage of the external elastic lamina and reduction in lumenal area over time, generally a period of *approximately* three to six months in humans." Attention is then drawn to column 4, lines 1-22, column 6, lines 4-10, column 6, lines 55-60, column 7, lines 36-43, column 8, lines 10-16, and column 10, lines 1-11 of Morris et al. in US Patent No. 5,516,781. Morris et al. clearly disclose of preventing the shrinkage of the external elastic lamina and reduction in lumenal area over time in column 6, lines 30-60. Moreover, a period of approximately three to six months in humans is discussed in column 10, lines 5-16. Therefore, given the specification and a reasonably broad interpretation of the claims would lead to the conclusion that Morris et al. clearly disclose the invention as claimed. Furthermore, providing a stent with a coating of rapamycin would clearly reduce

in-lesion lumen loss both proximate and distal to the medical device. Morris et al. clearly disclose rapamycin delivery via a stent as recited in claim 1 and in applying rapamycin to the stent would clearly affect the area immediate, proximal and distal to the stent.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the phrase, anti-proliferative/anti-inflammatory renders the claim indefinite for the scope is unclear. It is unclear whether the compound is an anti-proliferative compound, an anti-inflammatory compound or a compound that has properties to cause an anti-inflammatory and an anti-proliferative response.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. in US Patent No. 5,516,781.

Morris et al. disclose a method for the prevention of constrictive remodeling via controlled delivery, by release from an intraluminal medical device, a compound in therapeutic dosage amounts, as recited in claims 1-5; utilizing a compound to block the proliferation of fibroblasts in the vascular wall in response to injury, thereby reducing the formation of vascular scar tissue, as recited in column 4, lines 1-32; a compound has rapamycin, as recited in column 3, lines 45-50; and a compound that has analogs and congeners that bind a high-affinity cytosolic protein, FKBP12, and possesses the same pharmacologic properties as rapamycin. Since the current disclosure on page 9 recites, "Rapamycin as used throughout this application **shall include rapamycin**, rapamycin analogs, derivatives and congeners that bind FKBP12 and posses the same pharmacologic properties as rapamycin," the use of rapamycin is all encompassing. Morris et al. also disclose a compound to affect the translation of certain proteins involved in the collagen formation or metabolism; a drug delivery device having an intraluminal medical device; a therapeutic dosage of an agent releasably affixed to the intraluminal medical device for the treatment of constrictive vascular remodeling; and an intraluminal medical device that is a stent, as recited in claim 1.

Double Patenting

6. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/850,233. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the current application is merely a different wording representation. In some aspects the claims of the current application may be broader in some respects and add features in other aspects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/850,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current application is merely a different wording representation. In some aspects the claims of the current application may be broader in some respects and add features in other aspects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 09/850,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current application is merely a different wording representation. In some aspects the claims of the current application may be broader in some respects and add features in other aspects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-14 of copending Application No. 09/850,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current application is merely a different wording representation. In some aspects the claims of the current application may be broader in some respects and add features in other aspects.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/575,480. Although the conflicting claims are not identical, they are not patentably distinct from each other because merely a broader representation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
February 3, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700